

## UNITED STATE DEPARTMENT OF COMMERIPATENT and Trademark Office

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SERIAL NUMBER FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO 07/841,910 02/26/92 WARD  $\Gamma$ 1280-4014-US EXAMINER CRANE I 18M1 DAVID A KALOW ART UNIT PAPER NUMBER LIEBERMAN & NOWAK 292 MADISON AVE., 8TH. FLOOR 31 NEW YORK, NEW YORK 10017 1803 DATE MAILED: 05/19/93 This is a communication from the examiner in charge of your application. COMMISSIONER OF PATENTS AND TRADEMARKS Responsive to communication filed on 2/11, 12, 26/92 -93 This action is made final. This application has been examined A shortened statutory period for response to this action is set to expire \_\_\_\_\_\_\_ month(s), \_\_\_\_\_\_ days from the date of this letter. Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133 A shortened statutory period for response to this action is set to expire.\_\_\_3 THE FOLLOWING ATTACHMENT(8) ARE PART OF THIS ACTION: 1. Notice of References Cited by Examiner, PTO-892. 2. Notice re Patent Drawing, PTO-948. Notice of Art Cited by Applicant, PTO-1449. 6. 🔲 \_ SUMMARY OF ACTION 1. 🗵 Claims 101-103, 110-113, 138, 148 and 152-163 ----- are pending in the application Of the above, claims \_\_ are withdrawn from consideration 2. 🖸 Claims 129 1-100, 104-109, 114-137, 139-147 and 149-151 have been cancelled. 3. Claims 4. 🖸 Claims 191-103, 110-113, 138, 148 and 152-163 ----- are rejected. are subject to restriction or election requirement. 7. This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes. 8. Formal drawings are required in response to this Office action. 9.  $\square$  The corrected or substitute drawings have been received on  $\_$ \_ . Under 37 C.F.R. 1.84 these drawings are acceptable. not acceptable (see explanation or Notice re Patent Drawing, PTO-948). 10. The proposed additional or substitute sheet(s) of drawings, filed on \_\_\_\_\_ has (have) been approved by the examiner. disapproved by the examiner (see explanation). . 11. The proposed drawing correction, filed on \_\_\_\_\_\_, has been approved. disapproved (see explanation). 12. Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has Deen received not been received been filed in parent application, serial no. \_\_ : filed on \_ 13. 

Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213. 14. Other

SN 841,910

Serial No. 07/841,910

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Art Unit 1803

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The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group 1800, Art Unit 1803.

The instant case has had claims 1–163 included throughout its history.

Claims cancelled include 1-100, 104-109, 113-137, 140-145 (amdts A-B), claims 146-147, 149-151 (Amdt. D), claim 139 (amdt E). Taken together all cancelled claims are as follows: 1-100, 104-109, 113-137, 139-147 and 149-151.

The claims remaining in the case are 101-103, 110-112, 138, 148 and 152-163. This is a total of 20 claims left for consideration.

The submission of a terminal disclaimer in the parent case (SN 130,097, paper no. 19) is noted, but is not applicable to the instant case. If applicant desires a terminal disclaimer to be considered, applicant is requested to submit a properly executed terminal disclaimer for the instant case. Applicant is advised to consult with Group 1800 paralegals (Ms. D. Moffett et al. at (703) 308–0196) for answers to any questions concerning changes recently implemented in terminal disclaimer practice.

Claims 101-103, 110-112, 138, 148 and 152-163 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the prior invention as set

forth in claims 1–21 of U.S. Patent No. 4,711,955. Although the conflicting claims are not identical, they are not patentably distinct from each other because the <u>instant</u> claims are directed to much of the same subject matter of the already patented claims.

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The obviousness-type double patenting rejection is a judicially established doctrine based upon public policy and is primarily intended to prevent prolongation of monopoly by prohibiting claims in a second patent not patentably distinct from claims in a first patent. *In re Vogel*, 164 USPQ 619 (CCPA 1970). A timely filed terminal disclaimer in compliance with 37 CFR 1.321(b) would overcome an actual or provisional rejection on this ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78(d).

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Applicant's arguments filed February 26, 1992 have been fully considered but they are not deemed to be persuasive.

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Applicant is requested to note that the submission of a competent request for terminal disclaimer must <u>precede</u> withdrawal of the rejection supra. Hence, the rejection is maintained and the instant office action made final in order to render the instant prosecution as compact as possible.

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Claim 138 is rejected under 35 U.S.C. 112, fourth paragraph, as being of improper dependent form for failing to further limit the subject matter of a previous claim.

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In claim 138 the subject matter, substituted nucleoside 3',5'-cyclic monophosphates, has no antecedent basis in claim 101.

Appropriate correction is requested.

Applicant's arguments with respect to claim 138 have been considered but are deemed to be moot in view of the new grounds of rejection.

Claims 101-103, 110-112, 138, 148 and 152-163 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 101, 110 and 156-157 the terms "composition comprising", "comprises at least three carbon atoms", and "further comprises" are incorrect. Applicant is requested to note that claims directed to chemical compounds are indefinite when terms using variations of the verb "to comprise" are included, because consequently said terms imply the presence of other component parts which are not defined in the instant claims; e.g. metes and bounds are indeterminant. In addition, the term "composition" implies more than one molecular component while the instant claims fail to indicate the nature of the additional component(s) molecule(s). And finally the term "at least" fails to provide any upper limit and also therefore implies failure to define metes and bounds. In claim 158 the term "comprises" and in claim 162 the term "comprising" are rejected for the same reasons as noted above.

In claim 157 the term "n" is used as a subscript but is not otherwise defined, i.e. the instant claim is therefore indefinite.

Appropriate correction is requested.

Applicant's arguments with respect to claim of record have been considered but are deemed to be moot in view of the new grounds of rejection.

Claim 138 is rejected under 35 U.S.C. 112, first paragraph, as the disclosure is enabling only for claims limited in accordance with the specific embodiments. See MPEP 706.03(n) and 706.03(z).

In claim 138 the subject matter claimed is expanded further to include 3',5'-cyclic monophosphates, a genus which is not represented by even a single specific embodiment.

Appropriate corrections are requested.

Applicant's arguments filed February 26, 1992 have been fully considered but they are not deemed to be persuasive.

Applicant is referred to the recent decision in *Amgen v. Chugai*, 18 USPQ 2d 1016, at p. 1026 wherein it seems that the absence of specific embodiments in reasonable proportion to the body of claimed subject matter was the basis for upholding the examiner's rejection, a situation which appears to be closely analogous in view of the vast array of compounds and their biochemical immunocomplexes being claimed herein, and applicant's reliance solely on the prior art for

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allegations in support of enablement. Applicant is requested to note that a patent is not a hunting license. It is well known and established that "law requires that disclosure in an application shall inform those skilled in the art how to use applicant's alleged discovery, not how to find out how to use it for themselves." In re Gardner et al., 166 USPQ 138 (CCPA 1970).

Claims 101–103, 110–112, 138, 148 and 152–163 are rejected under 35 U.S.C. 112, first and second paragraphs, as the claimed invention is not described in such full, clear, concise and exact terms as to enable any person skilled in the art to make and use the same, and/or for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 101, 110 and 156-157 the terms "purine", "deazapurine", and "pyrimidine" are unduly broad and indefinite in view of the vast arrays of structures these terms encompass in comparison with the very meager number of disclosed specific embodiments of the instant specification. Mere specification of the attachment points does not suffice in view of the potential for multiple substituent modifications of any of these generically disclosed heteroaromatic ring systems, many of which may be inoperative in the intended utility as disclosed by applicant's specification; e.g. there is no guidance as to the intended limits of substitution provide in the instant claims. Therefore, applicant is requested to limit the scope of the instant claims to the specific embodiments in order to i) more specifically define the metes and bounds of the instant invention and

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ii) eliminate the need for undue experimentation by the ordinary practitioner which would be required to determine the boundaries of the instant claimed subject matter.

In claims 101, 110 and 156-157 the descriptions of the variable "A" and attachments thereto such as "the detectable polypeptide" clearly encompass very large areas of subject matter totally unexplored by applicant. The metes and bounds of claimed subject matter are not readily decernable to the ordinary practitioner confronted with such terminology. And the very vastness of the subject matter encompassed clearly exceeds the scope of the specific embodiments within the instant disclosure.

In claim 148 the terms "A is a ligand" and dependent references thereto are both indefinite and unenabled in view one of ordinary skill's inability to determine which "ligand[s]" applicant intends to claim and the scope of the term "ligand." In claim 151 the terms "enzyme", "substrate", and "detectable product" and in claim 162 the term "a cofactor" are criticized for the same reasons.

Appropriate correction is requested.

Applicant's arguments filed February 26, 1992 have been fully considered but they are not deemed to be persuasive.

Applicant's amended claim language is noted and does represent an improvement. However, the rejection retained and added supra have been maintained in view of the BPAI and CCPA decisions noted supra.

Applicant is requested to note that the instant case presently has a complete set of references only for the foreign patents. In order to make certain that these references are not "lost in transit" examiner will retain said references, properly labeled, but separate from the case. All US patents are available and are being collected and copied. However, the remaining literature references are all missing from the case save for the most recently submitted three references. Applicant is requested to submit copies of all of the missing literature references in order to make the instant file complete.

10 Prior reviews of the prior art in parent cases did not produce any references cited that were found to constitute competent prior art. In the absence of a complete assembly of cited art, it is presumed that this remains the case.

Papers related to this application may be submitted to Group 1800 via facsimile transmission(FAX). The transmission of such papers must conform with the notice published in the Official Gazette (1096 OG 30, November 15, 1989). The telephone number for the FAX machines operated by Group 1800 is (703) 305-3014. The machine operator may be reached at (703) 308-4744.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner L. E. Crane whose telephone number is 703-308-4639.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1800 receptionist whose telephone number is 703-308-0196.

5 LECrane:lec

5/14/93

JOHNNIE R. BROWN
SUPERVISORY PATENT EXAMINER

ART UNIT 183